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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,985	09/05/2003	David J. Kyle	8717.0010	5651

7590 10/19/2004
Finnegan, Henderson, Farabow,
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Washington, DC 20005-3315

EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/654,985

Applicant(s)

KYLE, DAVID J.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to algal biomass compositions, classified in class 435, subclass 257.1.
 - II. Claims 17-27, drawn to methods of feeding an animal by administering to the animal a composition comprising an algal biomass and a heterologous protein, classified in class 424, subclass 93.1.
 - III. Claims 28-40, drawn to yeast biomass compositions, classified in class 435, subclass 255.1.
 - IV. Claims 41-51, drawn to methods of feeding an animal by administering to the animal a composition comprising a yeast biomass and a heterologous protein, classified in class 424, subclass 93.51.
 - V. Claims 52-64, drawn to fungal biomass compositions, classified in class 435, subclass 254.1.
 - VI. Claims 65-75, drawn to methods of feeding an animal by administering to the animal a composition comprising a fungal biomass and a heterologous protein, classified in class 424, subclass 93.5.
 - VII. Claims 76-85, drawn to bacterial biomass compositions, classified in class 435, subclass 252.1.

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VIII. Claims 86-97, drawn to methods of feeding an animal by administering to the animal a composition comprising a bacterial and a heterologous protein, classified in class 424, subclass 93.4.

For each of Groups I-VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and one each of inventions (A)- (B) or subgroups (i) or (ii).

The inventions of subgroups (A) and (B) represent the elected invention wherein the non-native protein is (A) a protein or peptide, or (B) an antibody or antibody fragment.

The inventions of subgroups (i) and (ii) represent the claimed invention wherein the composition comprises (i) the elected microbial cell and a protein or antibody, or (ii) the elected microbial cell, a protein or antibody, and a recombinant virus that expresses the protein or antibody.

For Groups II, IV, VI, and VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VIII, and, if one of Groups II, IV, VI, and VIII is elected, then election is also required to one of subgroups (1)-(6). Subgroups (1)-(6) represent the elected method, wherein the method is a method for feeding (1) fish, (2) crustaceans, (3) cattle, (4) pigs, (5) fowl, or (6) humans.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of subgroups (A) and (B) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each of the inventions has separate utility. For example, the compositions comprising antibodies are useful for providing a form of passive immunization against an infection, whereas the compositions comprising a protein or peptide may be useful for inducing an immune or other therapeutic response. Because the inventions have separate utilities, the inventions are distinct.

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3. The inventions of subgroups (i) and (ii) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combinations may rely on the combination of the microbial cell and a protein or antibody for patentability, rather than on the presence of the recombinant virus required in the subcombination. The subcombination has the same separate utility as the combinations. Additionally, the subcombination may also be used to induce the expression of the protein or antibody in an animal.

4. The inventions of Groups I, III, V, and VII, or of Groups II, IV, VI, and VIII are related as subcombinations disclosed as usable together in a single combination. See MPEP § 806.05(d). The subcombinations are distinct from each other if they are shown to be separately usable. Each of the Groups from each group set relates to products, or methods of using products, comprising a different microbial cell. In the instant case, the inventions of each of the indicated Groups have the same separate utility as either the other subcombinations with the group set. Because each of these subcombinations relates to a different composition, or to methods of using different compositions, the inventions of the different Group sets are distinct one from another.

5. The inventions of Groups I, III, V, and VII are related as products and processes of use with the inventions of Groups II, IV, VI, and VIII. The inventions can be shown to be distinct if

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either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the product claims is drawn to compositions comprising some cellular biomass, and a heterologous protein or antibody. The methods claims are each directed to methods of feeding an animal with such compositions. However, these compositions may also be used in other methods, such as for raising immune responses against the constituent cells and proteins, or for detecting antigens and antibodies in a sample. Because the products are useful in methods other than those claimed, the products and the claimed methods are distinct inventions.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

If the Applicant elected subgroup (A) above, the Applicant is additionally required to elect either one of the species of proteins/peptides listed in (e.g.) claim 11, or an immunogenic epitope as described in claim 12. E.g., the Applicant may elect that the protein/peptide is a cecropine, or a parasin, or an immunogenic epitope.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 17, 28, 41, 52, 65, 76, and 86 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

7. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend**

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from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

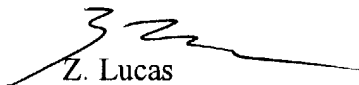
9. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 10/15/04
SUPERVISORY PATENT EXAMINER
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